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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,372	07/02/2001	Mark E. Van Dyke	KER020/4-005CON	3035

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/899,372	Van Dyke et al.
Examiner	**Art Unit**
Isis Ghali	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 28, 2002

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 55-96 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 55-96 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and election, both filed 2/28/2002.

Response to Election/Restriction

1. Applicant's election of species powder in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 55-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,270,791. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both of the patent and the instant claims are claiming a soluble peptide produced by the same process.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 55, 57, 59-61, 65, 69, 77, 79, 81-85, 87-89, 93, 94, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,495,173 ('173).

US '173 disclosed composition comprising keratin and method for its production. Keratin is an inherent peptide. The process included the steps of oxidizing animal or human hair, feathers, claws, horns, hoofs, scales and the like. Oxidizing agents included peroxides or peracetic acid. The oxidation is followed by neutralization then gel

filtration. Solvent used to solubilize keratin is ethanol or methanol. See col.2, lines 13-15, 21-24, 31-42; col.4, lines 52-55; col.5, lines 1-3, 53-54.

6. Claims 55-57, 59-61, 94 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,276,138 ('138).

US '138 disclosed a solubilized keratin, which is inherently a solubilized peptide, from animal hair or wool (abstract; col.65-67). The method of production included the steps of oxidation by hydrogen peroxide or peracetic acid; precipitation of a powder; and using solvent such as acetone, methanol or ethanol (col.3, lines 3-5, 21-24; col.4, lines 3, 20-28).

7. Claims 55, 57, 59-61, 65, 69-71, 73-84, 93 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,763,583 ('583).

US '583 disclosed a water soluble protein derived from human or animal hair (abstract; col.2, lines 15-18, 57-62; col.4, lines 49-50). The soluble protein is useful in cosmetics and medicines (col.6, lines 20-24). Protein is inherently a peptide. The soluble protein is produces by the process that comprised the steps of oxidation using hydrogen peroxide, neutralization of the produced aqueous solution followed by filtration (col.3, lines 20-25; col.4, lines 1-3, 14-23). Organic solvents are used such as

methanol and ethanol (col.5, lines 66-67; col.6, lines 15-17). The produced soluble protein is in the form of film (col.5, line 45).

8. Claims 55-57, 65, 69-71-84, 93 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,932,552 ('552).

US '552 disclosed a keratin hydrogel for wound dressing and scaffolding (abstract; col.2, lines 45-51; col.3, lines 19-25; col.5, lines 1-7). The hydrogel formed of soluble protein (protein is inherently a peptide). Derived from human or animal hair (col.2, lines 52-54). The hydrogel is formed by a process comprising the steps of oxidation using peracetic acid, filtration, drying, forming a powder (col.2, lines 57-64; col.3, lines 40-65). The process also included the step of neutralization by a base (col.2, lines 67-col.3, line 3).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 55-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '173, US '138, US '583 or US '552 each by itself or in combination with any of US 5,948,432 ('432), US 5,900,245 ('245), US 5,358,935 ('935), or FR 2540381 ('381).

The teachings of US 173, US '138, US '583 and US '552 are discussed in under 102 rejections above. The references, however, do not teach the keratin sheet for medical application, the use of the recipient' hair , or the wound dressing comprising peptide.

US '432 discloses an insoluble keratin sheets for wound dressing and scaffolding where you can add another additives that help healing (abstract; col.5, lines 19-24).

US '935 teaches that the hair for production of the protein is obtained from the recipient (abstract).

U&S 245 teaches a tissue sealant comprising peptides (see col.9, lines 53, 59; col.12, line 45; col.14, lines 8-10).

FR '381 teaches peptides derived from keratin used to stimulate the cell growth (abstract).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a wound dressing comprising peptide derived from the recipient' s hair and delivered on an insoluble keratin sheet. Motivation would arise from the knowledge in the dressing art or from the teaching of US '935 that the keratin derived from the recipient is non-antigenic; and from the teaching of FR '381 that the peptide stimulate the cell growth, and from the teaching of US '432 that the insoluble keratin sheet provides a non-antigenic sheet that can be shaped as needed before application to the wound and can be rehydrated to supple skin-like material (col.3, lines 12-24).

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,047,249 disclosed a composition and method for treating skin conditions and promoting wound healing comprising keratin-derived protein.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600